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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/494,149    01/28/00    MALECHA

S    A-67641-1/RF

EXAMINER

HM12/0411

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ART UNIT

PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b> 09/494,149	<b>Applicant(s)</b> MALECHA ET AL.	
	<b>Examiner</b> Peter Paras	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other:  |

Applicants' amendment filed on January 31, 2001 (Paper No. 8) has been entered. Claims 1-3 have been amended. Claims 12-18 have been cancelled. Claims 1-11 are pending and are under current consideration.

The following new grounds of rejection under 35 USC § 112, 2<sup>nd</sup> paragraph has been necessitated by Applicants' amendment to the claims:

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the limitation "capable of" renders the claim indefinite because the metes and bounds of the claim cannot be determined. Claim 1 is directed to a composition, but only recites the inclusion of a compound. It is unclear what elements are part of the composition which render it necessary to perform the required function.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-11 as originally filed are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The previous rejection under 35 U.S.C. 101 is maintained for the reasons of record advanced in Paper No. 6, on pages 3-4 of the Office action.

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that shrimp or prawns in nature do not naturally produce a population having a skewed percentage of females to males such as claimed. Applicants maintain that the shrimp or prawn population must be produced by breeding sexually reproductive neomale shrimp or prawn with a female of the same species. Applicants assert that sexually reproductive neomale shrimp or prawns do not exist in nature and therefore the population of shrimp or prawn recited in the claims does not exist in nature. See pages 3-4 of the amendment.

In response, the Examiner maintains that the claims read on a normal population of shrimp or prawns; meaning that the shrimp or prawns are genetically normal. In other words the process of breeding a neomale with a normal female does not make the resulting progeny genetically different from any other shrimp or prawns. The process may produce more females than males, but again all the progeny are normal. Furthermore, since the progeny of any species receive sex chromosomes from both the male and the female randomly, it often happens that one sex of the progeny is greater in number than the other. Accordingly, for the reasons of record and as discussed in the preceding paragraph the rejection under 35 U.S.C. 101 is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 as originally filed or amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Malecha et al (1992, Aquaculture, 105, 201-218) in view of Okuno et al (1997, Zoological Science, 14: 837-842) and Nagamine (1980, Gen. Comp. Endocrinol., 41: 442-457). The previous rejection under 35 U.S.C. 103(a) is maintained for the reasons of record advanced in Paper No. 6, on pages 4-6 of the Office action.

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that the references do not teach every limitation of the rejected claims. Applicants argue that Malecha does not teach an isolated shrimp or prawn androgenic polypeptide or a method of using the same polypeptide to produce a sexually reproductive neomale. Applicants argue that Okuno only teaches isolation of androgenic hormone from terrestrial isopods which are distantly related to shrimp or prawns and that Okuno never produces a sexually reproductive neomale *A. vulgare* or let alone a sexually reproductive neomale shrimp or prawn. Applicants argue that Nagamine does not make up the deficiencies of Malecha or Okuno. Applicants assert that while Nagamine teaches implantation of AG tissue into female prawns (*Macrobrachium rosenbergii*), neomales were never produced by this method.

The Examiner asserts that in response to applicant's argument that the cited references do not teach all the claimed embodiments of the rejected claims alone or in combination, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). For example, Nagamine teaches that the androgenic glands (and the androgenic hormone produced by the androgenic glands) function similarly in Amphipoda, Isopoda, and Decapoda (shrimp, prawns). See the Office action on page 6. Okuno teaches that androgenic gland hormone can be isolated from the androgenic glands of isopods by HPLC. Malecha teaches that implanting the androgenic gland (AG) into female prawns results in the production of neomales; the implanted androgenic gland produces a hormone that is responsible for differentiation of primary and secondary sex characteristics. See Malecha page 202. As Nagamine has suggested that the androgenic glands of Amphipoda, Isopoda, and Decapoda (shrimp, prawns) function similarly, and as Malecha has established that the androgenic gland secretes androgenic hormone, it would have been obvious to expect that androgenic hormone could be isolated from prawn androgen glands using the method of Okuno and then introduced into prawns to produce neomales according to Okuno and Malecha. As such the cited references teach the critical elements necessary to make the claimed invention.

Applicants argue that there is no motivation to combine the references of record, and that there would have been no reasonable expectation of success to make the claimed invention using the cited references. Applicants argue that Okuno merely masculinized a female *A. vulgare* by injecting AGH and that *A. vulgare* is only distantly related to shrimp and prawns. Applicants further assert that the mere suggestion by Nagamine that androgenic glands from isopods, amphipods, and decapods may perform similar functions does not provide any reasonable expectation that shrimp or prawn androgenic hormone would successfully produce a sexually reproductive neomale shrimp or prawn. Applicants are of the opinion that the combination of cited references at best piques the skilled artisan's curiosity for further experimentation.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it was known in the art that a functional similarity between the androgenic glands of isopods, amphipods, and decapods exists as discussed by Nagamine. It was also well known in the art that the Crustacean androgenic gland produces and secretes androgenic hormone as taught by Malecha; furthermore implantation of the prawn androgenic gland into female prawns results in the production of neomale prawns that are sexually

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reproductive (see Malecha, and Office action on page 5). Finally, Okuno teaches isolation of androgenic hormone from the androgenic glands of the isopod *A. vulgare* and subsequent injection of the isolated hormone into female *A. vulgare*. It would have been obvious in view of the cited references to expect to isolate androgenic hormone from the androgenic glands of prawns with a reasonable expectation of success as Malecha has taught that the prawn androgenic gland secretes androgen hormone and Okuno has taught a method for isolating androgenic hormone from the androgenic gland of a related species as suggested by Nagamine. Furthermore, Malecha has demonstrated that implanting androgenic gland tissue in female prawns produces neomales through the effects of secreted androgenic hormone, but with a high mortality rate of the implanted females due to the effects of surgery. Okuno has taught that androgenic hormone can be injected into female *A. vulgare*. Furthermore, as Malecha sought to reduce the mortality rate of female prawns receiving an implant of androgenic gland tissue by improving surgery techniques (see Malecha on page 213 and the Office action on page 6) there would have been sufficient motivation to isolate prawn androgenic hormone and inject the isolated hormone into female prawns to produce neomales as it was an art-recognized goal to control and manipulate sex-ratios in cultured populations of prawns for substantial benefit to commercial prawn aquaculture (as suggested by Malecha on page 202). As such the references provide ample motivation, as discussed above, to make the claimed invention.

Accordingly, the previous rejection under 35 U.S.C. 103(a) is maintained for the reasons of record and as discussed in the preceding paragraphs.

### Conclusion

**No claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinckney whose telephone number is (703) 305-3553.

Peter Paras, Jr.

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